

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,  
AND IRBESARTAN PRODUCTS  
LIABILITY LITIGATION**

**This Document Relates to All Actions**

MDL No. 2875

Honorable Robert B. Kugler,  
District Court Judge

Honorable Karen M. Williams,  
Magistrate Judge

Honorable Thomas Vanaskie  
(Ret.), Special Discovery Master

**THE ZHP PARTIES' BRIEF IN OPPOSITION  
TO PLAINTIFFS' MOTION TO COMPEL**

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## I. INTRODUCTION

Throughout this litigation, the ZHP Parties have worked tirelessly to comply with every discovery order issued by this Court, and the Court has noted on several occasions that the ZHP Parties have acted in good faith with respect to their discovery obligations. *See e.g.*, [Dkt. 1482](#) at 17 (“In this case, ZHP has demonstrated good faith.”). In the midst of a global pandemic, and facing numerous cross-border discovery obstacles, the ZHP Parties have demonstrated to this Court time and again their commitment to complying with discovery orders in a timely, fulsome, and transparent fashion, including by asking employees of ZHP and its subsidiary, Shanghai SynCores Technologies, Inc. (“SynCores”), to travel outside of mainland China to Macau for lengthy depositions despite the threat of COVID-19, as well as collecting and timely producing millions of pages of documents under an extraordinarily aggressive production schedule.

Even after fulfilling their Court-ordered document production obligations, the ZHP Parties *voluntarily* agreed to additional discovery requests from Plaintiffs in an effort to work cooperatively rather than burden this Court with disputes and additional motions. The ZHP Parties did so notwithstanding that these additional document requests and custodial files exceeded the scope of discovery ordered by former Magistrate Judge Schneider.

Regrettably, Plaintiffs have failed to reciprocate the ZHP Parties' cooperative and good faith approach to discovery.<sup>1</sup> Rather than engage in *fact* finding, it is now evident that Plaintiffs' goal was and remains to utilize the discovery process for purposes neither contemplated nor condoned by the Federal Rules.

The instant motion is no exception. Plaintiffs' motion to compel should be denied in toto because:

- Plaintiffs have failed to articulate either a factual or legal basis on which this Court can infer spoliation, which is required in order to compel the production of the ZHP Parties' litigation hold letters. The factual record clearly demonstrates that the ZHP Parties were aware of their obligation to preserve documents and data relevant to this litigation and took affirmative steps to ensure that such data was preserved;
- Plaintiffs have repeatedly mischaracterized the Court's prior discovery orders, and granting their motion to compel would only embolden them to continue to engage in this type of improper conduct; and
- The ZHP Parties have complied, and continue to comply, with this Court's prior and more recent orders regarding document production, and Plaintiffs' reliance on simple document counts in support of their motion rather than any substantive analysis of produced documents only further demonstrates their unwillingness to engage in a

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<sup>1</sup> For example, Plaintiffs have often failed to satisfy their meet and confer obligations prior to bringing discovery disputes to this Court. *See, e.g.,* [Dkt 684](#) at 4; [Dkt. 866](#) at 7-8. Plaintiffs' latest request for certain standard operating procedures ("SOPs") that contain document retention policies, which Plaintiffs raised *for the first time* in their motion, is yet another example of this conduct. The ZHP Parties are willing to search for and produce certain SOPs listed in Plaintiffs' motion that contain document retention policies and are responsive to Plaintiffs' original document requests, and would have communicated this to Plaintiffs if they had simply attempted to meet and confer on this issue prior to filing their motion.

substantive, meaningful review of the more than 370,000 documents produced by the ZHP Parties.

As described below, the record demonstrates that the ZHP Parties have complied with their discovery obligations throughout this litigation. At the same time, Plaintiffs have shown in a variety of contexts that they have no interest in expending the time and resources necessary to translate and carefully review the millions of pages of documents they insist are critical to proving their case. The instant motion is a transparent attempt by Plaintiffs to lay the groundwork for a baseless spoliation motion that they no doubt hope will relieve them of doing the hard work of building their case through translating and reviewing the hundreds of thousands of Chinese language documents already produced by simply claiming that what they “need” to prove their case has either been lost or destroyed.

For these reasons, the Court should reject Plaintiffs’ motion to compel in its entirety.

## II. LEGAL ARGUMENT

### A. Plaintiffs have failed to make any showing of spoliation.

1. Plaintiffs’ admission that the 2,274 documents they characterize as “missing” have *actually been produced* demonstrates that they are not “lost” pursuant to Federal Rule of Civil Procedure 37(e).

Plaintiffs have devoted a significant portion to their motion to “analyzing” the document counts of various custodians in arguing that ZHP has either failed to produce and/or destroyed 2,274 emails, the earliest of which is dated January 21,

2010. See [Dkt. 1405](#) at 6. Specifically, Plaintiffs contend that because the custodians listed on page 6 of their brief are included on these emails, but did not produce them from their own custodial files, the Court should infer that these emails have either been improperly withheld or destroyed. This argument lacks both factual and legal merit, and the case cited by Plaintiffs in support of their contention is inapposite.

Federal Rule of Civil Procedure 37(e) provides that “[i]f electronically stored information that should have been preserved in the anticipation or conduct of litigation is lost because a party failed to take reasonable steps to preserve it, and it cannot be restored or replaced through additional discovery,” the Court may impose certain remedies, including, as Plaintiffs have requested here, the production of litigation hold letters. Fed. R. Civ. P. 37(e); *see also Major Tours, Inc. v. Colorel*, No. 05-3091, 2009 WL 2413631, at \*2 (D.N.J. Aug. 4, 2009). Importantly, however, “[b]ecause electronically stored information often exists in multiple locations, loss from one source may often be harmless when substitute information can be found elsewhere.” Fed. R. Civ. P. 37(e), Advisory Committee note to 2015 amendments.

Here, Plaintiffs’ argument is devoid of merit, as the law is clear that spoliation cannot be inferred where a custodian’s purportedly “lost” document is produced from another custodian. *See Oracle Am., Inc. v. Hewlett Packard Enter. Co.*, 328 F.R.D. 543, 552 (N.D. Cal. 2018) (holding that documents deleted by Oracle’s Co-



Chief Executive Officer were not “lost” within the meaning of Rule 37(e) because they were produced by another Oracle custodian). In permitting Plaintiffs to collect documents from more than 80 ZHP Party custodians, the Court undoubtedly took into consideration that over a 10 year period, documents that may have not been saved by some custodians may have been saved by others. Further, Plaintiffs fail to account for the fact that certain custodians may have deleted or chose not to save email communications during the *decade* prior to the commencement of this litigation.<sup>2</sup>

In asserting that they have made a showing of spoliation and therefore are entitled to the ZHP Parties’ litigation hold letters, Plaintiffs rely solely on Magistrate Judge Schneider’s opinion in *Major Tours, Inc. v. Colorel*, No. 05-3091, 2009 WL 2413631, at \*2 (D.N.J. Aug. 4, 2009). However, in finding that the plaintiff in that case had made a “preliminary” showing of spoliation, Judge Schneider made clear that his decision was based on the testimony of two of the defendants’ corporate witnesses who had failed to adhere to litigation hold notices:

***In making this finding the Court relies on defendants’ Fed. R. Civ. P. 30(b)(6) testimony in which Plaintiffs asked Defendants’ witnesses about their litigation hold efforts.*** When Michael Colorel, Principal Investigator for the CBIU, was asked on February 8, 2007 whether he was advised by his lawyers to preserve his email communications

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<sup>2</sup> As shown in Plaintiffs’ motion and exhibit 29 thereto, the ZHP Parties have already and fully complied with the Court’s prior order to produce the dates and recipients of litigation hold notices as of December 30, 2019.

regarding claims of racial discrimination, he answered that he was ‘probably’ told by his lawyers to do so, but additionally admitted, ‘I don’t sa[v]e anything.’ Maryann Mazon, another Rule 30(b)(6) witness, testified on April 3, 2008 that no one ever talked to her about creating a litigation hold policy and that she was not sure what a litigation hold policy was.

*Id.* at \*3. (emphasis added and internal citations omitted).

In stark contrast to the defendants in *Major Tours*, each of the ZHP Parties’ 17 corporate and fact witnesses who were questioned about their efforts to preserve documents related to this litigation testified that they were aware of their obligations and took steps to preserve such information. For example, Linda Lin, ZHP’s Director of Regulatory Affairs, testified that when her computer broke during the pendency of this litigation, the information from her prior laptop was transferred to her current laptop, and that she was permitted to keep her prior laptop for preservation purposes:

24:22 Q. How long have you had that  
24:23 laptop for use at work?  
24:24 A. I started using this laptop  
25:1 April 1st, 2019. I remember very clearly  
25:2 because the date is April 1st.  
25:3 Q. What computer were you using  
25:4 for work before April 1, 2019?  
25:5 A. It was Surface. Microsoft  
25:6 Surface.  
25:7 Q. Was that a laptop?  
25:8 A. It can be called as a laptop.  
25:9 It can also be called as a tablet.  
25:10 Q. When did you first using the  
25:11 Microsoft Surface?  
25:12 A. Around 2014.

25:13 Q. Why did you switch from the  
25:14 Microsoft Surface to the Dell laptop on  
25:15 April 1, 2019?

25:16 A. Because at that time I had  
25:17 trouble turning on Microsoft Surface.  
25:18 Sometimes it would take me 15 minutes to  
25:19 reboot the Microsoft Surface. I couldn't  
25:20 stand it.

\*\*\*

26:2 Q. Was the data and documents on  
26:3 the Microsoft Surface moved over to the Dell  
26:4 laptop when you changed computers in  
26:5 April 2019?

26:6 A. Basically, yes. I still keep  
26:7 that Microsoft Surface now.

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27:16 Q. Was your Dell laptop and your  
27:17 Microsoft Surface tablet collected so that  
27:18 the information and data could be provided to  
27:19 us as part of this litigation, to your  
27:20 knowledge?

27:21 A. That's correct. That is why I  
27:22 always keep this Microsoft Surface.

Ex. A, Excerpt of 5-4-21 Linda Lin Deposition at 24:22 – 27:22. *See also*,  
*e.g.* Exs. B through E, Excerpts of 5-27-21 Jun Du Deposition at 15:15 – 20:1;  
4-20-21 Min Li Deposition at 37:8 – 39:8, 45:2 – 46:5; 4-5-21 Eric Gu  
Deposition at 21:21 – 22:7; and 3-10-21 Hai Wang Deposition at 22:21-24:17,  
27:23-28:4, respectively.

As each of the “missing” 2,274 documents was, in fact, produced from another ZHP Party custodian, and because each of the ZHP Party witnesses testified that they adhered to the litigation hold instructions they were provided, Plaintiffs have failed to make even a “preliminary” showing of spoliation under Rule 37(e) and *Major Tours*.

2. In contrast to Plaintiffs’ unsupported conspiracy theories, the evidence demonstrates that Dr. Min Li effectively preserved the majority of data on his broken laptop, and ZHP subsequently produced responsive information therefrom to Plaintiffs.

Perhaps the most perplexing allegation of Plaintiffs is that “ZHP also continues to pretend that the obviously irregular manner in which the [July 27, 2017 email authored by Jingshen Lin (“July 27, 2017 Email”)] was produced is not a real issue, but objectively viewed, it is apparent that the email was not meant to be produced (along with everything related) but slipped through due to the metadata error for the copy that was produced.” [Dkt. 1405](#) at 5. While Plaintiffs do not explain how the metadata of the email relates to their allegation that the document “was not meant to be produced” or to Dr. Min Li’s broken laptop, the *actual evidence* produced by ZHP, as well as Dr. Li’s deposition testimony, demonstrate that ZHP and Dr. Li took affirmative steps to preserve the data on the laptop, and that responsive data was properly collected, reviewed, and produced to Plaintiffs.

During his deposition, Dr. Li directly addressed all of Plaintiffs’ questions regarding his broken laptop:

33:22 Q. You started working with ZHP in  
33:23 2014, right?

33:24 A. Yes. September of 2014, yes.

34:1 Q. Were you given any sort of a  
34:2 computer at that time to do your work for  
34:3 ZHP?

34:4 A. Yes.

34:5 Q. What type of computer were you  
34:6 given when you started?

34:7 A. Originally it's a ThinkPad,  
34:8 Lenovo ThinkPad, but that computer broke  
34:9 down. Now I have a Microsoft, like what,  
34:10 ProBook.

34:11 Q. You said you were given a  
34:12 Lenovo ThinkPad when you started, and then it  
34:13 broke. When did it break?

34:14 A. When did it break. That's a  
34:15 very good question. It broke during --  
34:16 actually during a trip. I don't remember  
34:17 exactly.

34:18 When did it break. Probably  
34:19 somewhere between 2017 to 2018, but, you  
34:20 know, I don't have an accurate, you know,  
34:21 recollection exactly, like, which year.

34:22 Q. When your computer broke, did  
34:23 you notify your company that you needed a new  
34:24 computer?

35:1 A. Oh, yeah, mm-hmm.

35:2 Q. Who did you notify?

35:3 A. IT.

35:4 Q. And they got you a new  
35:5 computer?

35:6 A. Yes.

35:7 Q. There would be a record within  
35:8 the company of you asking for a new computer  
35:9 and getting that computer. I assume  
35:10 something like that gets documented, right?

35:11 A. Oh, sure, sure, uh-uh.

35:12 Q. So if we need to know when your  
35:13 computer broke and when you got your new

35:14 computer, the company should be able to  
35:15 provide that information, right?  
35:16 A. Yeah. If I ask, they should be  
35:17 able to provide, yes.

Ex. C, Excerpt of 4-20-21 Min Li Deposition at 33:22 – 35:17.

Subsequently, Plaintiffs requested documentation about Dr. Li's broken laptop,<sup>3</sup> and ZHP produced the documentation it had in its files, including a contemporaneous receipt dated June 5, 2018 reflecting a payment made by ZHP to a third party, Hangzhou Guanxiang Technology Co. Ltd, related to the service of "hard disk data recovery" for Dr. Li's laptop.

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<sup>3</sup> As Plaintiffs note in their brief, they also requested information regarding a laptop that was lost by Eric Gu, General Manager of ZHP's non-party subsidiary, SynCores. As Dr. Gu testified, he lost his laptop in 2015 during a flight from the U.S. to China. See Ex. D, Excerpt of 4-5-21 Eric Gu Deposition at 26:3 – 27:1. SynCores has not been able to locate the correspondence it received from China Eastern Airlines regarding Dr. Gu's lost laptop in 2015. However, as Dr. Gu testified, he was not involved in the manufacturing process change which SynCores assisted ZHP in developing in 2011, as he did not join SynCores until 2014. *Id.* at 17:7 – 15; 34:5 – 35:11. Rather, he testified as a 30(b)(6) corporate witness regarding SynCores' assistance to ZHP in developing the manufacturing process change. *Id.* at 30:22 – 31:12; 60:5 -10.

浙江增值税专用发票 No 14709215 178

开票日期: 2018年06月05日

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规格型号	单位	数量	单价	金额	税率	税额
技术服务费	个	1	820.75	820.75	6%	49.25
合计				¥820.75		¥49.25

价税合计(大写) 捌佰柒拾圆整 (小写) ¥870.00

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ZHP02730425, Ex. F (English translation included at Ex. G); *see also* ZHP02730426, Ex. H (English translation included at Ex. I)(contemporaneous email chain dated May 21, 2018 wherein Dr. Li requests that a colleague decode an attachment for him because his laptop is broken) and ZHP02730423, Ex. J (English translation included at Ex. K)(ZHP internal application for payment form for Hangzhou Guanxiang Technology Co. Ltd. related to fees for technical services, dated June 6, 2018).

This contemporaneous documentation also supports Dr. Li's testimony regarding ZHP's handling of his laptop after it broke:

- 36:4 Q. When you said the computer  
36:5 broke on a trip, what happened to the  
36:6 computer?  
36:7 A. It just could not start, so I  
36:8 think eventually it turns out to be, you  
36:9 know, a hard drive failure.  
36:10 Q. What happened to the data that  
36:11 was on the computer?

36:12 A. I would say, according to the  
36:13 IT guys -- well, quite a few documents  
36:14 actually became permanently damaged, *but the*  
36:15 *majority of them [were] able to be restored,*  
36:16 yeah.

Ex. C, Excerpt of 4-20-21 Min Li Dep. at 36:4-16 (emphasis added).

The metadata produced with the July 27, 2017 Email is consistent with the documents produced by ZHP and Dr. Li's testimony on this issue. For example, the source path for the location of where the document was stored on Dr. Li's new computer is titled "**/F/Old Desktop/Projects/Irbesartan 厄贝沙坦,**" (emphasis added), and the document has a creation date of June 18, 2018—all of which are fully consistent with Dr. Li's testimony (and the documentation outlined above) that his files were transferred from his old computer to his new one in June of 2018. *See* Ex. L (copy of metadata produced with ZHP00190573).<sup>4</sup>

In short, Dr. Li's testimony regarding his broken laptop is supported by the contemporaneous documentation evidencing the steps taken by ZHP to preserve all of the information thereon. In addition, that documents were collected, reviewed, and produced from a folder specifically labelled as coming from Dr. Li's prior laptop, and filed under a project for *irbesartan* (as opposed to valsartan),

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<sup>4</sup> Although Plaintiffs make a passing reference to the "limited" nature of the production related to Dr. Li's laptop (*see* [Dkt. 1405](#) at 9-10), they have failed to articulate what, if any, additional documents they are requesting.



demonstrates the painstaking efforts that the ZHP Parties undertook to preserve, collect and produce all potentially relevant documents, and Plaintiffs have failed to cite any evidence otherwise.

3. The relatively low number of responsive documents in the files of custodians who were not involved in the development or manufacture of valsartan is not evidence of spoliation.

Over a period of several months in late 2019, Plaintiffs and Defendants engaged in an extensive negotiation process regarding, among other electronic discovery issues, the identity of custodians from whom documents would be produced. *See* [Dkt. 243](#); [Dkt. 292](#). This process included a meet and confer held before Magistrate Judge Schneider on October 23, 2019, at which time Plaintiffs were permitted to question ZHP's Vice Chairman, Jun Du, for over five hours about ZHP's departmental and management structure, the roles of numerous ZHP employees responsible for various aspects of the development, manufacture, and sale of valsartan API and finished dose products. *See* [Dkt. 274](#). Following this extensive exchange of information, the Court ordered that more than 80 employees of the ZHP Parties be designated as custodians for discovery purposes. *See* [Dkt. 324](#).

In light of Plaintiffs' claims and the ZHP Parties' defenses, the ZHP custodians from whom the court ordered document production were generally involved in one of the following areas: 1) process development for valsartan API; 2) the manufacturing processes for valsartan API and finished dose products; 3) quality

assurance and quality control for valsartan API and finish dose products; 4) valsartan API sales; and 5) the discovery of and testing for nitrosamines in valsartan API.

As the Court is well-aware, this initial list of custodians did not include a number of custodians that ZHP voluntarily agreed to collect documents from in May 2021. *See* [Dkt. 1228](#). While the ZHP Parties did not believe these individuals were likely to have information responsive to Plaintiffs' document requests given their limited and/or lack of involvement in the development, manufacture, or sale of valsartan products (i.e., the reason they were not identified as relevant custodians), ZHP nonetheless agreed to produce documents from these additional custodians in the spirit of transparency and cooperation. So, it should come as no surprise that this group of individuals who were not identified as custodians and had little or no involvement with valsartan products, ultimately had limited documents and data responsive to Plaintiffs' document requests.

This is especially true of those custodians working at CEMAT, including Jingshen Lin. As Dr. Min Li testified, CEMAT did not exist until after he joined ZHP in 2014. *See* Ex. C, Excerpt of 4-20-21 Min Li Dep. at 71:13 - 72:3. As described in Dr. Li's testimony, CEMAT was created "[t]o solve the most challenging technical problems encountered from research and development to scale up and manufacture of drug substances and finished products, particularly those related to process impurities, degradation products, and solid state and

polymorphism.” *Id.* at 75:14-76:5. However, while *today* CEMAT would have been tasked with researching process impurities such as those that occurred during the zinc chloride process used to manufacture valsartan API (*Id.* at 75:24 – 76:5), at the time the zinc chloride process was developed in 2011, CEMAT *did not exist*.<sup>5</sup>

Given CEMAT’s lack of involvement in the development of the zinc chloride process for manufacturing valsartan API, it is to be expected that the custodians working there and other custodians who have little involvement in the key issues in this case have relatively few responsive documents, and, clearly, no factual basis exists on which the Court can infer spoliation as argued by Plaintiffs.

**B. Plaintiffs have repeatedly and knowingly mischaracterized this Court’s discovery orders.**

1. This Court has not ordered the production of Maggie Kong’s custodial file, and ZHP maintains its objection to the file’s production.

Of great concern to the ZHP Parties, Plaintiffs have stated in correspondence and in its submissions to the Court, that the Court has ordered the custodial file of Maggie Kong to be produced when, as the Court is well aware, *there is no such*

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<sup>5</sup> Similarly, Baohua Chen’s lack of involvement in the key events of this case have been extensively briefed and documented by the ZHP Parties. *See* Dkt. 1244, 1246, 1247-2, and 1295. Thus, the relatively small number of responsive documents in his custodial file is consistent with his limited involvement in the development, manufacture and sale of valsartan. However, as Plaintiffs have raised (for the first time in their motion) an issue with respect to the metadata accompanying Mr. Chen’s production, the ZHP Parties will produce a supplemental overlay containing this metadata to address Plaintiffs’ concerns.

*order*. Plaintiffs have failed to cite any such order on the docket, and have instead cited this Court's instruction to the parties that Ms. Kong's custodial file be *collected*, not produced. As even the Court hearing transcripts cited by Plaintiffs make clear, the Court permitted the ZHP Parties to assert their objections on proportionality grounds in this brief, in response to Plaintiffs' motion to compel. *See* Ex. M, 5/12/2021 Tr. 32:15-33:1; and Ex. N, 6/25/21 Tr. 30:15-17.

As set forth in the ZHP Parties' prior objections, Ms. Kong is the Chief of Staff to the President of ZHP, Baohua Chen; and she did not join ZHP until late 2017, *several years after many of the events at issue in this case*. *See* [Dkt. 1237](#) at 6-7. As a member of the President's staff, she has no direct role in the development, manufacturing, testing or sale of valsartan, nor does she have any regulatory responsibilities at ZHP. *Id.* Plaintiffs have indicated that their primary goal in collecting Ms. Kong's custodial file is to locate the dates and times of certain meetings involving Mr. Chen; however, the ZHP Parties have confirmed that Ms. Kong does not keep a hardcopy calendar, and the ZHP Parties' production to date demonstrates that calendaring software is rarely, if ever, used among ZHP's employees, including Ms. Kong. *See, e.g.*, Exs. C, A, and B, Excerpts of 4-22-21 Min Li Deposition at 593:23 – 594:19; 5-4-21 Linda Lin Deposition at 16:15 – 17:13; and 5-27-21 Jun Du Deposition at 85:18 – 86:8, respectively. Further, the Court has already ordered, and ZHP has produced, the files of Baohua Chen, and

any responsive information in Ms. Kong's documents is likely to be duplicative of the information produced from Mr. Chen's files. *See Arconic Inc. v. Novelis Inc.*, No. 17-1434, 2019 WL 5802365, at \*20 (W.D. Pa. Sept. 6, 2019) (denying request to add custodian because employee "was working at the direction of" an existing custodian).

In addition, because the ZHP Parties do not have a general counsel, Ms. Kong serves as the primary contact with the ZHP Parties' attorneys; accordingly, responsive documents within her custodial file contain privileged information, and, for reasons set forth below, a detailed review of her custodial file would therefore be unduly burdensome. *Id.* Fed. R. Civ. P. 26(b)(1) ("Parties may obtain discovery regarding any *nonprivileged matter* that is relevant to any party's claim or defense and *proportional to the needs of the case*, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and *whether the burden or expense of the proposed discovery outweighs its likely benefit.*"). After collecting Ms. Kong's custodial file, applying the court-ordered search terms rendered 37,579 document hits, inclusive of families; of that number, 16,339 documents, inclusive of families, were hits for privilege terms. Accordingly, *more than 43%* of the documents at issue are likely to be privileged.

In light of the testimony of ZHP's witnesses that the information Plaintiffs claim they are seeking (i.e., calendar and meeting invitations) does not exist in Ms. Kong's custodial file; Plaintiffs' failure to articulate what unique information they are seeking from Ms. Kong that has not been captured by Mr. Chen's production of documents; and the burden of reviewing the extraordinarily high number of privileged documents in Ms. Kong's files, it is disproportionate to the needs of this case to compel the ZHP Parties to review and produce Ms. Kong's custodial file. Accordingly, Plaintiffs' request should be denied.

2. The ESI Protocol does not require Defendants to collect and review all electronic devices of the Court-ordered custodians.

Plaintiffs' misstatements regarding the requirements of this Court's discovery orders also extends to its misleading characterization of the ESI Protocol entered in this matter. The cited reference to cell phone and/or smart phone data in the ESI Protocol is in the definitions section, which, unsurprisingly, provides that such data falls within the definition of "electronically stored information." [Dkt. 125](#) at 2. Consistent with their ongoing pattern of misrepresenting the Court's prior discovery rulings and orders, *Plaintiffs have omitted a key provision of this section of the protocol* that immediately follows the lone sentence cited by Plaintiffs in their motion; this provision provides:

This list is neither exhaustive, *nor does it represent that such ESI exists within the parties' data sources or that it will be produced.* The

parties agree to meet and confer regarding any disputes relating to relevancy, proportionality, or production issues before submission of any disputes to the court.

[Dkt. 125](#) at 2. Accordingly, given that the only basis Plaintiffs have asserted for the production of this information is a non-existent “requirement” of the ESI Protocol, Plaintiffs’ request must be denied.

Despite knowing since the ZHP’s Parties’ production was substantially complete in late 2020 that none of ZHP’s custodians produced cell phone or smart phone data, Plaintiffs have only recently claimed that such data should have been produced. They have never engaged in any meaningful meet and confer with the ZHP Parties on the subject, and have not articulated a valid factual or legal basis for the production of such information.

Further, as the ZHP Parties have explained on many more than one occasion to Plaintiffs, and as each of the ZHP witnesses has testified in their respective depositions, none of the ZHP custodians have cell phones or smart phones issued or owned by ZHP. *See e.g.* Ex. C, Excerpt of 4-20-21 Min Li Deposition at 53:5 – 54:12; and Ex. O, 5-18-21 Jie Wang Deposition at 21:22 – 22:9. To the extent Plaintiffs seek the production of data held on the *personal* devices of ZHP Party custodians, this Court cannot grant Plaintiffs’ request given that Plaintiffs have failed to subpoena this data from the ZHP Parties’ employees, none of whom are parties to

this case.<sup>6</sup> In addition, more than 370,000 documents have already been produced to Plaintiffs by the ZHP Parties, and they have failed to articulate how the production information on any custodian's personal devices would be non-duplicative of the vast information already provided to them or proportional to the needs of the case.

In sum, as the purported basis for Plaintiffs' request for cell phone data is a complete mischaracterization of the ESI Protocol, and is not supported with any evidence that such data is germane to the issues in this litigation, Plaintiffs' request should be denied.

**C. The ZHP Parties have fulfilled their obligations with respect to the remaining information at issue.**

1. The ZHP Parties have fully complied with their obligations regarding the production of testing data, and Plaintiffs have failed to establish why any additional testing data should be produced.

There is no question that the ZHP Parties have abided by the Macro-Discovery Order. The ZHP Parties have gone to great lengths to ensure that they have produced documents that were related to the presence of nitrosamine in valsartan, irrespective of the country standard by which it was manufactured. However, with respect to testing records, including the nitrosamine testing records Plaintiffs have now put at

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<sup>6</sup> Further, to the extent Plaintiffs seek to obtain this information from individuals in China, even if they were able to serve a subpoena through the Hague Convention protocol, China's privacy laws would likely prevent such information from being obtained and disclosed.



issue, the order specifically requires the parties to meet and confer regarding the scope of testing records. *See* [Dkt. 303](#) at 4. Accordingly, throughout the winter and spring of 2020, counsel for the ZHP Parties and Plaintiffs did exactly that, and negotiated the scope of production regarding testing documents. In particular, Plaintiffs were informed that valsartan API batch records and the nitrosamine testing records for those batches were extremely cumbersome and expensive to produce because they are large files that exist only in hard copy. As a result, the parties subsequently agreed to limit the scope of the ZHP Parties' production to Plaintiffs. *See* Ex. P, September 2020 email between counsel.

The Court gave Plaintiffs an opportunity to "prioritize" certain categories of documents that Plaintiffs insisted were absolutely necessary to review prior to the document production deadline, and among those documents prioritized by Plaintiffs' were ZHP nitrosamine testing records. *See* Dkt. 416 (MDL Text Order). Accordingly on August 28, 2020, ZHP produced all of its hard copy nitrosamine records for USDMF grade valsartan, and the production log produced by the ZHP Parties clearly identified these documents as "Nitrosamine testing records" on their production log. *See* Ex. Q. Soon thereafter, on September 13, 2020, counsel for the ZHP Parties confirmed with counsel for Plaintiffs that all of the testing records had been produced, and provided counsel with the specific production volume numbers. *See* Ex. P, September 2020 email between counsel.

Despite Plaintiffs' representation to the Court last year that it was imperative that nitrosamine testing records be prioritized in ZHP's production, during the most recent meet and confer process it became clear that Plaintiffs had never reviewed the documents specifically identified last year as nitrosamine testing records, and the ZHP Parties had to repeatedly identify their location in ZHP's production (despite the fact that they are clearly identified in the ZHP Parties' production log). *See* Ex. N, 6/25/21 Tr. 33:25-34:7; 35:1-6; 44:22. In an effort to assist Plaintiffs, during the meet and confer process ZHP agreed to search for a more detailed summary of the nitrosamine testing results, but made clear to Plaintiffs that the ZHP Parties would not agree to any additional hard copy scanning of non-USDMF grade testing records.

After that search, the ZHP Parties informed Plaintiffs during the meet and confer process that they could not locate any chart that is more detailed than the one that Plaintiffs already have in their possession (and which is cited in Plaintiffs' motion), resulting in Plaintiffs' request in the instant motion. However, not only is Plaintiffs' request for additional testing records untimely, Plaintiffs have made absolutely no showing as to how thousands of testing records for API *that was never used for products sold in the United States* is either relevant to their claims or

proportional to the needs of this case.<sup>7</sup> Accordingly, Plaintiffs request for additional testing records should be denied.

2. The ZHP Parties have searched for, collected, reviewed, and produced documents referencing “TC-201729” as well as the irbesartan improvement project documents requested by Plaintiffs.

Based on the Plaintiffs’ lack of any meaningful description of the documents produced as search term hits for “TC-201729” and the documents produced related to the irbesartan improvement project (and, similarly, Plaintiffs’ failure to articulate what they believe is missing based on the actual content of those documents), the ZHP Parties can only conclude that Plaintiffs, once again, have failed to perform any meaningful review of these documents, which are primarily in Chinese. As the ZHP Parties have repeatedly explained to Plaintiffs, the documents requested by Plaintiffs are clearly identified in production volumes ZHP038 and ZHP044.<sup>8</sup> Plaintiffs’ reliance on simple document counts in support of their argument rather than any

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<sup>7</sup> As noted in the chart cited by Plaintiffs, ZHP manufactured significantly more valsartan API for use in products sold in countries other than the United States in comparison to the amount of valsartan API manufactured for the U.S. market. *See Dkt. 1405* at 11. Consequently, requiring the production of test results for API sold outside of the United States would require significantly more time and expense to produce than that associated with the production of documents related to valsartan API sold in products for the U.S. market.

<sup>8</sup> As part of their ongoing quality control efforts, the ZHP Parties have identified a limited number of additional documents related to the irbesartan improvement project that it will produce to Plaintiffs on or before August 18, 2021.

substantive analysis of the actual documents themselves is insufficient to demonstrate that the ZHP's Parties' production is deficient. Accordingly, Plaintiffs' motion to compel the production of these documents should be denied.

3. There are no additional meeting minutes or calendar invites to be produced.

Even a cursory analysis of the ZHP Parties' document production demonstrates that almost none of its employees use calendaring software, which was confirmed during the depositions of several ZHP employees. *See e.g.*, Exs. C, A, and B, Excerpts of 4-22-21 Min Li Deposition at 593:23 – 594:19; 5-4-21 Linda Lin Deposition at 16:15 – 17:13; and 5-27-21 Jun Du Deposition at 85:18 – 86:8, respectively. In addition, despite Plaintiffs' protestations otherwise, all responsive meeting minutes in the custodian's files have been produced, including those documents related to what Plaintiffs have characterized as "Min Li's meeting with "multinational companies." *See e.g.*, ZHP00661878, ZHP00304048.<sup>9</sup> Accordingly, Plaintiffs' motion to compel the production of these documents should be denied.

### **III. CONCLUSION**

For all of the forgoing reasons, the ZHP Parties respectfully request that Plaintiffs' Motion to Compel be denied in its entirety.

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<sup>9</sup> ZHP00661878 and ZHP00304048 are contained in production volumes ZHP025 and ZHP022, respectively.

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Respectfully submitted,

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